percentage of solution specifications, without acknowledging that Oxone includes compounds in addition to potassium peroxymonosulfate. For purposes of generating formulations, it is important to note that Oxone (formula weight of 614 g/mol) comprises 42.8 % (minimum per manufacturer) - 49.5% (maximum theoretical) w/w potassium peroxymonosulfate.

12. Specifically, several solutions of McNeil samples C-02, C-06, C-12 and E-07 were prepared in accordance with the foregoing, each solution having 20% potassium peroxymonosulfate ($KHSO_5$) plus ketone (ignoring the other compounds of Oxone in the solution). Our reference Formulation F1 is McNeil Sample C-02, Formulations F2 and F3 are McNeil Sample C-06, Formulation F4 is McNeil Sample C-12, and Formulations F5 and F6 are McNeil Sample E-07. The table indicates (a) the molar ratio of $KHSO_5$ to ketone; (b) the percentage of $KHSO_5$ and ketone in solution (ignoring the additional Oxone compounds); and (c) the percentages of buffer and water in solution (calculated assuming the caroate is $KHSO_5$, and ignoring the additional compounds of Oxone in solution). The pH of each solution was measured with the results set forth in the table.

REF. FORMULA #	F1	F2	F3	F4	F5	F6
	C-02 (CSA)	**C-06 (AC)**	**C-06 (AC)**	**C-12 (CSA)**	**E-07 (CSA)**	**E-07 (CSA)**
Oxone	0.83	0.83	0.83	0.83	0.84	0.83
Ketone	1.67	1.67	1.67	1.67	1.67	1.67
Buffer Soln.	0.10	0.00	0.00	2.08	8.33	8.33
Water	8.23	8.33	8.33	6.25	0	0
Ketone FW	232	58	58	232	232	232
Molar Ratio $KHSO_5$: Ketone	0.38	0.09	0.09	0.38	0.38	0.38
% $KHSO_5$ + Ketone	20%	20%	20%	20%	20%	20%
% Buffer	1%	0%	0%	20%	80%	80%
% Water	79%	80%	80%	60%	0%	0%
pH instant	1.12		2.19	1.3		1.5
pH 10 mins.	1.1	1.82	2.09	1.31	1.31	1.49

13. Thus, it is evident that each of these McNeil samples have a pH below 2.5, including C-12 and E-07 where McNeil reports that the larger amount of buffer therein inhibits the bactericidal /

sporicidal effectiveness of the dioxirane (See McNeil Col. 11, Lines 55-58, and Col. 12, Lines 31-33). Furthermore, when acetone is used as the ketone (see F2 and F3), the solution has a higher pH than solutions including CSA as the ketone, even without the buffer. Finally, the inclusion of 20% or even 80% buffer solution in the formulation (see F4, F5 and F6) only marginally increases the pH of the solution over that of a solution comprising 1% buffer solution (F1).

14. Several additional solutions of McNeil Samples C-02, C-06, C-12 and E-07 were prepared in accordance with the foregoing, each solution having 20% Oxone plus ketone in solution. Our reference Formulation F7 is McNeil Sample C-02, Formulation F8 is McNeil Sample C-06, Formulation F9 is McNeil Sample C-12, and Formulation F10 is McNeil Sample E-07. Molar ratios and percentages in solution were calculated as above, except the Oxone is considered caroate, ignoring that Oxone consists of compounds in addition to $KHSO_5$. The pH of each solution was measured with the results set forth in the following table.

REF. FORMULA #	F7	F8	F9	F10
	C-02 (CSA)	***C-06 (AC)***	***C-12 (CSA)***	***E-07 (CSA)***
Oxone	1.11	1.11	1.11	1.11
Ketone	1.11	1.11	1.11	1.11
Buffer Soln.	0.11	0	2.22	8.89
Water	8.78	8.89	6.67	0
Ketone FW	232	58	232	232
Molar Ratio Oxone:Ketone	0.38	0.094	0.38	0.38
% Oxone + Ketone	20%	20%	20%	20%
% Buffer	1%	0%	20%	80%
% Water	79%	80%	60%	0%
pH instant	1.54	2.13	1.55	2
pH 10 mins.	1.58	2.11	1.57	2.02

15. Thus, even with an adjustment in Oxone and ketone, these results were consistent with the pH testing in the first table presented herewith. Again, each of the McNeil samples have a pH below 2.5, including the buffer-inhibited samples C-12 and E-07. Furthermore, when acetone is used as the ketone (see F8), the solution again has a higher pH even without the buffer. Finally, the

inclusion of 20% or even 80% buffer solution in the formulation (see F9 and F10) at best marginally increases the pH of the solution over that of a solution comprising 1% buffer solution (F7).

16. Finally, solutions of McNeil Sample C-03 were prepared in accordance with the foregoing, and molar ratios and percentages in solution were calculated as above, with Oxone being considered caroate in Formulation F11 (ignoring that Oxone consists of compounds in addition to $KHSO_5$); and in Formulation F12 with $KHSO_5$ being considered caroate (wherein the Oxone compounds other than $KHSO_5$ were ignored in solution). The pH of each formulation was measured and the results of such measurements are set forth in the table.

REF. FORMULA #	*F11*	*F12*
	C-03 (4HB[3])	*C-03 (4HB)*
Oxone	1.29	1.06
Ketone	0.97	1.58
Buffer Soln.	0.11	0.11
Water	8.92	8.31
Ketone FW	88	88
Molar Ratio $KHSO_5$:Ketone	na	0.19
Molar Ratio Oxone:Ketone	0.19	na
% $KHSO_5$ + Ketone	na	20.0%
% Oxone + Ketone	20 .0%	na
% Buffer	1.0%	1.0%
% Water	79.0%	79.0%
pH instant	2.03	2.06
pH 10 mins.	2.05	2.09

17. From these results it is evident that like the other McNeil samples, Sample C-03 also has a pH below 2.5.

18. One can easily surmise that the pH of example C-15N would not fall within the pH range of the present claims (pH 5-9) because the buffer is specifically stated as pH 4.

[3] 4HP used in McNeil was not available in Applied Research Associates' laboratory, and would be difficult for Applied Research to obtain because of the laboratory's location on a military base; thus 4HB which was readily available was used instead. 4HB possess the same functionality with an alkyl-OH and ketone group and would be expected to have a very similar effect on pH in solution as 4HP. The formula weight of 4HB is 88.1g/mol

19. Thus, McNeil is only able to support low-pH (below 2.5 pH) buffered, dioxirane-generating formulations in his working examples. Further, McNeil expressly states that increasing the amount of buffer in his dioxirane-generating formulation interferes with the bactericidal benefits of the formulation.

20. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

Carrie Delcomyn

Carrie Delcomyn

2/3/09

Date

Dinsmore&Shohl LLP
ATTORNEYS

FACSIMILE TRANSMITTAL

from MONIKA J. HUSSELL
Direct: 304-357-9924 / Fax: 304-357-0919 / monika.hussell@dinslaw.com

February 5, 2009

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Patent Case:
Inventor(s): Delcomyn, et al.
Title: CHEMICAL AND BIOLOGICAL WARFARE AGENT DECONTAMINATING METHODS USING DIOXIRANE-PRODUCING FORMULATIONS
Serial No.: 10/687,864
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Art Unit: 1796

Pages: (including cover) 8

Comments: Examiner Delcotto,

Pursuant to our prior discussions, attached please find the affidavit of Carrie Delcomyn (an inventor in the above referenced case) regarding pH testing of the prior art solutions.

If there are any problems in receiving this transmission, please call the fax room at (304) 357-0900 immediately. Thank you.